CLAIMS

1. An intraorally rapidly disintegrable tablet which comprises fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent, D-mannitol and a disintegrator.

2. The intraorally rapidly disintegrable tablet as claimed in Claim 1, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

3. The intraorally rapidly disintegrable tablet as claimed in Claim 1 or 2, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

4. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 3, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

5. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 4, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

6. The intraorally rapidly disintegrable tablet as

claimed in any one of Claims 1 to 4, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

7. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 6, further containing a lubricant.

8. The intraorally rapidly disintegrable tablet as claimed in Claim 7, wherein the lubricant is contained only on the surface of the tablet.

9. The intraorally rapidly disintegrable tablet as claimed in Claim 7 or 8, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

10. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 9, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

11. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 10, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

12. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 11, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

13. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 12, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

14. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 13, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

15. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 14, wherein the hardness of the tablet is 20N or higher.

16. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 1 to 15, wherein the disintegration time in oral cavity is 30 seconds or less.

17. A process for producing an intraorally rapidly disintegrable tablet which comprises mixing fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent, D-mannitol and a disintegrator to prepare a material for compression molding, and subjecting the material to compression molding.

18. The process as claimed in Claim 17, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

19. The process as claimed in Claim 17 or 18, wherein

the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

20. The process as claimed in any one of Claims 17 to 19, wherein the whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

21. The process as claimed in any one of Claims 17 to 20, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

22. The process as claimed in any one of Claims 17 to 20, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

23. The process as claimed in any one of Claims 17 to 22, wherein the material for compression molding contains a lubricant.

24. The process as claimed in any one of Claims 17 to 23, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

25. The process as claimed in Claim 23 or 24, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty

acid ester and talc.

26. The process as claimed in any one of Claims 17 to 25, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

27. The process as claimed in any one of Claims 17 to 26, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

28. The process as claimed in any one of Claims 17 to 27, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

29. The process as claimed in any one of Claims 17 to 28, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

30. The process as claimed in any one of Claims 17 to 29, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

31. An intraorally rapidly disintegrable tablet which is produced by mixing fine granules prepared by granulating a mixture of a water-soluble pharmacologically active ingredient and an adsorbent D-mannitol and a disintegrator to prepare a material for compression molding and subjecting the material to compression molding.

32. The intraorally rapidly disintegrable tablet as claimed in Claim 31, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

33. The intraorally rapidly disintegrable tablet as claimed in any one of Claim 31 or 32, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

34. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 33, wherein whole or a part of the D-mannitol is a primary particles and the specific surface area of the primary particle is 1.0 m^2/g or less.

35. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 34, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

36. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 34, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

37. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 36,wherein the material for compression molding contains a lubricant.

38. The intraorally rapidly disintegrable tablet as

claimed in any one of Claims 31 to 37,wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

39. The intraorally rapidly disintegrable tablet as claimed in Claim 37 or 38, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

40. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 39, wherein the material for compression molding contains at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

41. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 40, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the fine granules is 1:10 to 10:1.

42. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 41, wherein the compounding ratio of the fine granules in the tablet is 1 to 50% by weight.

43. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 42, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

44. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 43, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

45. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 44, wherein the hardness of the tablet is 20N or higher.

46. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 31 to 45, wherein the disintegration time in oral cavity is 30 seconds or less.

47. A process for producing an intraorally rapidly disintegrable tablet which comprises granulating a mixture of a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator to prepare a material for compression molding, and subjecting the material to compression molding.

48. The process as claimed in Claim 47, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

49. The process as claimed in Claim 47 or 48, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

50. The process as claimed in any one of Claims 47 to 49, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

51. The process as claimed in any one of Claims 47 to 50, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

52. The process as claimed in any one of Claims 47 to 50, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

53. The process as claimed in any one of Claims 47 to 52, wherein the material for compression molding contains a lubricant.

54. The process as claimed in any one of Claims 47 to 53, wherein the compression molding is carried out using a compression molding machine in which a lubricant is previously applied on the surface of punch and the die.

55. The process as claimed in Claim 53 or 54, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

56. The process as claimed in any one of Claims 47 to 55, wherein the compression molding material containis at least one member selected from the group consisting of flavoring agents,

sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

57. The process as claimed in any one of Claims 47 to 56, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent in the compression molding material is 1:10 to 10:1.

58. The process as claimed in any one of Claims 47 to 57, wherein the compounding ratio of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

59. The process as claimed in any one of Claims 47 to 58, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

60. The process as claimed in any one of Claims 47 to 59, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

61. An intraorally rapidly disintegrable tablet which comprises a water-soluble pharmacologically active ingredient, an adsorbent, D-mannitol and a disintegrator.

62. The intraorally rapidly disintegrable tablet as claimed in Claim 61, wherein the adsorbent is at least one member selected from the group consisting of calcium silicate, light anhydrous silicic acid, synthetic aluminum silicate, silicon dioxide and magnesium metasilicate aluminate.

63. The intraorally rapidly disintegrable tablet as

claimed in Claim 61 or 62, wherein the disintegrator is at least one member selected from the group consisting of crospovidone, low-substituted hydroxypropylcellulose, croscarmellose sodium and carboxymethylcellulose.

64. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 63, wherein whole or a part of the D-mannitol is a primary particle and the specific surface area of the primary particle is 1.0 m^2/g or less.

65. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 64, wherein the solubility of the water-soluble pharmacologically active ingredient in water is 1 mg/ml or more.

66. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 64, wherein the water-soluble pharmacologically active ingredient is pravastatin sodium.

67. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 66, containing a lubricant.

68. The intraorally rapidly disintegrable tablet as claimed in Claim 67, wherein the lubricant is contained only on the surface of the tablet.

69. The intraorally rapidly disintegrable tablet as claimed in Claim 67 or 68, wherein the lubricant is at least one member selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, stearyl alcohol, sodium stearyl fumarate, sucrose fatty acid ester and talc.

70. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 69, further containing at least one member selected from the group consisting of flavoring agents, sweeteners, perfumes, coloring agents, stabilizers, fluidizing agents, anti-oxidants and co-solubilizers.

71. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 70, wherein the compounding ratio of the water-soluble pharmacologically active ingredient to the adsorbent is 1:10 to 10:1.

72. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 71, wherein the compounding ratio of the water-soluble pharmacologically active ingredient and the adsorbent in the tablet is 1 to 50% by weight.

73. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 72, wherein the compounding ratio of the D-mannitol in the tablet is 20 to 99% by weight.

74. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 73, wherein the compounding ratio of the disintegrator in the tablet is 0.5 to 30% by weight.

75. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 74, wherein the hardness of the tablet is 20N or higher.

76. The intraorally rapidly disintegrable tablet as claimed in any one of Claims 61 to 75, wherein the disintegration time in the oral cavity is 30 seconds or less.